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## Sunitinib

pronounced as (soo ni' ti nib)

### IMPORTANT WARNING:

Sunitinib may cause serious or life-threatening damage to the liver. Tell your doctor if you have or have ever had liver disease or problems with your liver. If you experience any of the following symptoms, call your doctor immediately: itching, yellow eyes and skin, dark urine, or pain or discomfort in the right upper stomach area. Your doctor may have to decrease your dose of sunitinib or permanently or temporarily stop your treatment.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain blood tests before and during your treatment to be sure that it is safe for you to take sunitinib and to check your body's response to the medication.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with sunitinib and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking sunitinib.

### Why is this medication prescribed?

Sunitinib is used to treat gastrointestinal stromal tumors (GIST; a type of tumor that grows in the stomach, intestine (bowel), or esophagus (tube that connects the throat with the stomach) in people with tumors that were not treated successfully with imatinib (Gleevec) or people who cannot take imatinib. Sunitinib is also used to treat advanced renal cell carcinoma (RCC, a type of cancer that begins in the cells of the kidneys). Sunitinib is also used to help prevent the return of RCC in people who have RCC that has not spread and have had a kidney removed. Sunitinib is also used to treat pancreatic neuroendocrine tumors (pNET, a type of tumor that begins in certain cells of the pancreas) in people with tumors that have worsened and cannot be treated with surgery. Sunitinib is in a class of medications

called kinase inhibitors. It works by blocking the action of the abnormal protein that signals cancer cells to multiply. This helps stop or slow the spread of cancer cells and may help shrink tumors.

## How should this medicine be used?

Sunitinib comes as a capsule to take by mouth with or without food. For the treatment of gastrointestinal stromal tumors (GIST), or for the treatment renal cell carcinoma (RCC), sunitinib is usually taken once a day for 4 weeks (28 days) followed by a 2-week break before beginning the next dosing cycle and repeated every 6 weeks for as long as your doctor recommends. For the prevention of RCC, sunitinib is usually taken once a day for 4 weeks (28 days) followed by a 2-week break before beginning the next dosing cycle and repeating every 6 weeks for 9 cycles. For the treatment of pancreatic neuroendocrine tumors (pNET), sunitinib is usually taken once daily. Take sunitinib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take sunitinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not split, chew, or crush them. Do not open the capsules.

You may need to take one or more capsules at a time depending on your dose of sunitinib.

Your doctor may decrease your dose or temporarily or permanently stop your treatment if you experience certain side effects. This depends on how well the medication works for you and the side effects you experience. Talk to your doctor about how you are feeling during your treatment with sunitinib.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking sunitinib,

- tell your doctor and pharmacist if you are allergic to sunitinib, any ingredients of sunitinib capsules, or any other medications. Ask your pharmacist or check the manufacturer's patient information sheet (Medication Guide) for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: certain antibiotics such as clarithromycin (Biaxin, in Prevpac), rifampin (Rifadin, Rimactane, in Rifamate, in Rifater), rifabutin (Mycobutin), rifapentine (Priftin), and telithromycin (Ketek); certain antifungals such as itraconazole (Onmel, Sporanox), ketoconazole, and voriconazole (Vfend); dexamethasone; medications for diabetes; certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) including atazanavir (Reyataz, in Evotaz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); nefazodone; certain medications for seizures such as carbamazepine (Carbatrol, Eptol, Equetro, Tegretol, Teril), phenobarbital, and phenytoin (Dilantin, Phenytek). Also tell your doctor if you are taking or have taken alendronate (Binosto, Fosamax), etidronate, ibandronate (Boniva), pamidronate, risedronate (Actonel, Atelvia), or zoledronic acid injection (Reclast, Zometa). Other medications may also interact with sunitinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor and pharmacist what herbal products you are taking, especially St. John's wort. Do not take St. John's wort while taking sunitinib.
- tell your doctor if you have or have ever had a bleeding problem; a blood clot in the lungs; a QT interval prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death); a slow, fast, or irregular heartbeat; a heart attack; heart failure; high blood pressure; seizures; low blood sugar or diabetes; low levels of potassium or magnesium in your blood; problems with your mouth, teeth or gums; or kidney, thyroid, or heart disease.
- tell your doctor if you are pregnant, plan to become pregnant, or if you plan to father a child. You or your partner should not become pregnant while you are taking sunitinib. If you are female, you will need to have a pregnancy test before you start treatment, and you should use birth control to prevent pregnancy during your sunitinib treatment and for 4 weeks after your final dose. If you are male, you and your partner should use birth control to prevent pregnancy during your treatment with sunitinib and for 7 weeks after your final dose. Talk to your doctor about birth control methods that you can use during your treatment. Sunitinib may decrease fertility in men and women. However, you should not assume that you or your partner cannot become pregnant. If you or your partner become pregnant while taking sunitinib, call your doctor. Sunitinib may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed during your treatment with sunitinib and for 4 weeks after your final dose.
- if you are having surgery tell the doctor or dentist that you are taking sunitinib. Your doctor will probably tell you to stop taking sunitinib at least 3 weeks before your scheduled surgery because it can affect wound healing. Your doctor will tell you when to start taking sunitinib again after your surgery.
- you should know that sunitinib may cause your skin to turn yellow and your hair to lighten and lose color. This is probably caused by the yellow color of the medication and is not harmful or painful.
- you should know that sunitinib may cause high blood pressure. Your blood pressure should be checked regularly while you are taking sunitinib.
- you should know that sunitinib may cause osteonecrosis of the jaw (ONJ, a serious condition of the jaw bone), especially if you have dental surgery or treatment while you are taking the medication. A dentist should examine your teeth and perform any needed treatments, including cleaning or fixing ill-fitted dentures, before you start to take sunitinib. Be sure to brush your teeth and clean your mouth properly while you are taking sunitinib. Tell your doctor or dentist if you have or have had mouth, teeth, or jaw pain; mouth sores or swelling; numbness or a feeling of heaviness in the jaw; or any loose teeth. Talk to your doctor before having any dental treatments while you are taking this medication.

## What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

## What should I do if I forget a dose?

If you miss a dose of sunitinib by less than 12 hours, take the missed dose as soon as you remember it and then take the next dose at the scheduled time. However, if you miss a dose by more than 12 hours, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Sunitinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- weakness
- nausea
- vomiting
- diarrhea
- constipation
- heartburn
- gas
- hemorrhoids
- pain, irritation, or burning sensation of the lips, tongue, mouth or throat
- dry mouth
- change in the way things taste
- loss of appetite
- weight changes
- hair loss
- thin, brittle fingernails or hair
- slow speech
- pale or dry skin
- shaking
- heavy, irregular, or missed menstrual periods
- depression
- difficulty falling asleep or staying asleep
- dryness, thickness, cracking, or blistering of skin on the palms of the hands and the soles of the feet
- muscle, joint, back, or limb pain
- frequent nosebleeds
- bleeding from your gums
- unusual discomfort in cold temperatures

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately:**

- unusual bruising or bleeding
- bloody or black and tarry stools

- blood in the urine
- vomit that is bright red or looks like coffee grounds
- coughing up blood
- stomach pain, swelling, or tenderness
- headache
- fever
- swelling, tenderness, warmth, or redness of a leg
- swelling of the feet or ankles
- rapid, irregular, or pounding heartbeat
- dizziness or fainting
- decreased alertness or concentration
- confusion
- depression
- nervousness
- seizures
- vision changes
- chest pain or pressure
- extreme tiredness
- shortness of breath
- pain with deep breathing
- unexplained weight gain
- decreased urination
- cloudy urine
- swelling of the eyes, face, lips, tongue, or throat
- rash
- hives
- blistering or peeling skin or inside of mouth
- difficulty swallowing or breathing
- hoarseness

Sunitinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain tests such as electrocardiograms (EKG, test that records the electrical activity of the heart), echocardiograms (test that uses sound waves to measure your heart's ability to pump blood), and urine tests before and during your treatment with sunitinib to be sure it is safe for you to take sunitinib, and to check your body's response to the medication.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Sutent<sup>®</sup>

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